

DBS

- 1968
 - Human & nonhuman primate diploid cells
 - Leonard Hayflick / Albert Sabin
 - Transfusion safety
 - Leukemia
 - Hepatitis
 - J. Garrett Allen
 - Paid vs unpaid donors
- 1972
 - DBS → BoB

DBS Lessons Learned

- Politics can be decisive
- Potential transmission of infectious agents
 - Too permissive (blood)
 - Too restrictive (cells)
- Middle ground
- Outside support for decisions & policy

Late 1970s – early 1980s

- Continuous cell lines
 - Interferon
 - rDNA proteins
 - Monoclonal antibodies
- Issues
 - Transmissible agent(s)
 - DNA
- Public meetings with consensus building
 - Points to Consider

AIDS

- Clinical condition
- HIV
 - 24 April 1984 announcement by Sec. Heckler
 - Blood test within 1 year
 - Vaccine in 18-24 months
 - 2 March 1985 approval of first HIV test
 - UK and France

W H O

- 1986 conference
- Safety as a moving target
 - New risks or agents
 - Advances in technology
 - Coincident or unrelated

C J D

- Europe
 - 1995: no product recalls
 - 1997: nvCJD
 - 1998: recalls related to nvCJD
 - Supply implications
 - Benefit/risk analyses
- USA
 - 1997/8: >300 batches withdrawn
 - 1998: policy change, consistent with Europe

History

- 1901 – tetanus in horse antiserum
- 1942 – hepatitis B from human serum in yellow fever vaccine
- 1955 – Cutter incident
- 1960 – SV-40 in polio vaccines
- 1970s
 - Hepatitis B from human plasma protein fraction
 - Rabies from human corneas
 - CJD from human pituitaries and dura mater
- 1980s – hepatitis viruses and HIV
- 1990s – prions
- Current
 - West Nile virus
 - Animal retroviruses

100 Years of Lessons

- Be prepared for surprises
- Don't think you know it all
- Problems are likely unless:
 - Strict control on manufacturing process and starting materials
 - Up-to-date technology
- Primary human cells and tissues
- Conventional wisdom is not always right

The Next 100 Years

- Basic elements of successful regulation
 - Good science
 - Knowledgeable staff
- Remember the lessons of the 1st 100 years